

Practitioner's Docket No. 46342/55,965

IN THE UNITED STATES DESIGNATED OFFICE (DO/US)

<u>PCT/JP99/06873</u>	<u>08 December 1999</u>	<u>09 December 1998</u>
INTERNATIONAL APPLICATION NO.	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED

BETACELLULIN MUTEIN
TITLE OF INVENTION

Takashi ITO, Mitsuyo KONDO, Yoko TANAKA, Masayuki KOBAYAH, Koichi IGARASHI,
Reiko SASADA and Osamu NISHIMURA
APPLICANT(S) FOR DO/US

Box PCT
Assistant Commissioner for Patents
Washington, D.C. 20231
ATTENTION: DO/US

**COMPLETION OF FILING REQUIREMENTS
FOR INTERNATIONAL APPLICATION ENTERING NATIONAL
STAGE IN U.S. DESIGNATED OFFICE (DO/US) UNDER 35 U.S.C. 371**

(check and complete the following item, if applicable)

- [X] This replies to the Notice of Missing Requirements under 35 U.S.C. § 371 and 37 C.F.R. 1.494 (FORM PCT/DO/EO/905).
[X] A copy of FORM PCT/DO/EO/905 accompanies this response.

WARNING: *Filing requirements, including translation of the international application, the declaration, the national fee and the payment of all the surcharge(s) in connection with the filing of these items after twenty (20) months from the priority may be met within twenty-two (22) months from the priority date. Failure to comply with these requirements Will result in abandonment. The provisions of 37 CFR 1.136 for extensions of time do not apply to the 22 month period. 37 CFR 1.61(b).*

NOTE: *The completion of the filing requirements within 22 months (instead of 20 months) from the priority date results from the Commissioner exercising his judgment under the authority granted under 35 USC 371(d). The filing receipt will show the actual date of receipt of the last item completing the entry into the national phase. See 37 CFR 1.491 which states: "An international application enters the national stage when the applicant has filed the documents and fees required by 35 USC 371(c) within the periods set forth in § 1.494 and § 1.495."*

CERTIFICATE OF MAILING/TRANSMISSION (37 C.F.R. 1.8a)

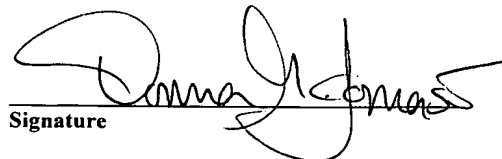
I hereby certify that this correspondence is, on the date shown below, being:

MAILING

- ☒ deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

FACSIMILE

- ☐ transmitted by facsimile to the Patent and Trademark Office.


Signature

Date: September 25, 2001

Donna M. Tomaso
(type or print name of person certifying)
under 35 USC 371--page 1 of 6)

WARNING: Where the items being submitted to complete the entry of the international application into the national phase are subsequent to 20 months from the priority date, the application is still considered to be in the international stage. If mailing procedures are utilized to obtain a date, the express mail procedure of 37 CFR 1.10 must be used (because international application papers are not covered by an ordinary certificate of mailing. 37 CFR 1.8(2)(xi)).

NOTE: Documents and fees must be clearly identified as a submission to enter the national stage under 35 USC 371. Otherwise, the submission will be considered as being made under 35 USC 111. 37 CFR 1.494(f).

DECLARATION OR OATH

- I. ☐ No original declaration or oath was filed. Enclosed is the original declaration or oath for this application.

NOTE: For surcharge fee for filing declaration after filing date, complete item IV(2).

NOTE: Acceptable minimums in the declaration in an ordinarily filed U.S. application for identification of the specification to which it applies are the name of the inventor and (1) serial number, (2) attorney docket number that was on the application as filed and the filing date, (3) title of the invention and filing date, (4) title of invention and reference to a specification that is attached to the declaration at the time of execution and filed with the declaration, or (5) title of invention and a statement by a registered attorney that the application filed in the PTO is the application that the inventor executed by signing the declaration. If identification (4) is used, it must be accompanied by a statement that the "attached" specification is a copy of the specification and any amendments thereto that were filed in the PTO to obtain the filing date. Such a statement must be a verified statement if made by a person not registered to practice before the PTO. Notice of September 12, 1983 (1035 O.G. 3).

NOTE: Another minimum found acceptable in the declaration is the filing date (i.e., date of express mail) and the express mail number, useful where the serial number is not yet known. But note the practice where the express mail deposit is a Saturday, Sunday or holiday within the District of Columbia. 37 CFR 1.10(c).

NOTE: 37 CFR 1.41(a) points out that "Full names must be stated, including the family name and at least one given name without abbreviation together with any other given name or initial."

(complete (a) or (b), if applicable)

Attached is a

- (a) ☐ Statement by a registered attorney that the application filed in the PTO is the application that the inventor executed by signing the declaration.
- (b) ☐ Statement that the "attached" specification is a copy of the specification and any amendments thereto that were filed in the PTO to obtain the filing date.

AMENDMENT

II. (complete as applicable)

- ☐ An amendment in accordance with 37 C.F.R. § 1.121 is attached.
- ☐ The attached amendment cancels claims _____ inclusively.

SMALL ENTITY STATUS

V. A statement that this filing is by a small entity

NOTE: See 37 CFR 1.28(a).

(check and complete applicable items)

- a. ☐ is attached.
was filed on _____ (original).
- b. ☐ A separate refund request accompanies this paper.

EXTENSION OF TIME

(complete (a) or (b), as applicable)

VI.

The proceedings herein are for a patent application. The provisions of 37 C.F.R. § 1.136(a) apply.

- (a) ☐ Applicant petitions for an extension of time, the fees for which are set out in 37 C.F.R. § 1.17(a)(1)-(4), for the total number of months checked out below:

<u>Extension (months)</u>	<u>Fee for over than small entity</u>	<u>Fee for small entity</u>
<input type="checkbox"/> one month	\$ 110.00	\$ 55.00
<input type="checkbox"/> two months	\$ 380.00	\$190.00
<input type="checkbox"/> three months	\$ 870.00	\$435.00
<input type="checkbox"/> four months	\$1,390.00	\$680.00

Fee \$ _____

If an additional extension of time is required, please consider this a petition therefore.

(check and complete the next item, if applicable)

- ☐ An extension for _____ months has already been secured. The fee paid therefore of \$ _____ is deducted from the total fee due for the total months of extension now requested.

Extension fee due with this request \$ _____

or

- (b) ☒ Applicant believes that no extension of term is required. However, this conditional petition is being made to provide for the possibility that applicant has inadvertently overlooked the need for a petition and fee for extension of time.

TOTAL FEE DUE

VII. The total fee due is:

Completion fee(s)	\$ 0.00
Extension fee (if any)	\$ 0.00
TOTAL FEE DUE	\$ 0.00

PAYMENT OF FEES

VIII.

☒ Enclosed is a check in the amount of \$ 0.00.
☐ Charge Account No. _____ in the amount of \$ _____.
A duplicate of this request is attached.

NOTE: Fees should be itemized in such a manner that it is clear for which purpose the fees are paid. 37 CFR 1.22(b).

AUTHORIZATION TO CHARGE ADDITIONAL FEES

IX.

WARNING: Accurately count claims, especially multiple dependent claims, to avoid unexpected high charges.

NOTE: "A written request may be submitted in an application that is an authorization to treat any concurrent or future reply, requiring a petition for an extension of time under this paragraph for its timely submission, as incorporating a petition for extension of time for the appropriate length of time. An authorization to charge all required fees, fees under § 1.17, or all required extension of time fees will be treated as a constructive petition for an extension of time in any concurrent or future reply requiring a petition for an extension of time under this paragraph for its timely submission. Submission of the fee set forth in § 1.17(a) will also be treated as a constructive petition for an extension of time in any concurrent reply requiring a petition for an extension of time under this paragraph for its timely submission." 37 CFR 1.136(a)(3).

NOTE: "Amounts of twenty-five dollars or less will not be returned unless specifically requested within a reasonable time, nor will the payer be notified of such amounts; amounts over twenty-five dollars may be returned by check or, if requested, by credit to a deposit account." 37 CFR 1.26(a).

- ☒ The Commissioner is hereby authorized to charge the following additional fees that may be required by this paper, and during the entire pendency of this application, to Account No. 04-1105
- ☒ 37 C.F.R. 1.492(a)(2), 1.492(a)(3), or 1.492(a)(5) (filing fees)
- ☒ 37 C.F.R. 1.492(b) (presentation of extra claims)

NOTE: Because additional fees for excess or multiple dependent claims not paid on filing, or on later presentation, must only be paid, or these claims cancelled by amendment prior to the expiration of the time period set for response by the PTO in any notice of fee deficiency (37 CFR 1.16(d)), it might be best not to authorize the PTO to charge additional claim fees, except possibly when dealing with amendments after final action.

- ☒ 37 C.F.R. 1.17 (application processing fees)
- ☒ 37 C.F.R. 1.17(a)(1)-(5) (extension fees pursuant to § 1.136(a)).

WARNING: While 37 CFR 1.17(a), (b), (c) and (d) deal with extensions of time under § 1.136(a), this authorization should be made only with the knowledge that: "Submission of the appropriate extension fee under 37 CFR 1.136(a) is to no avail unless a "quest or petition for extension is filed." (Emphasis added). Notice of November 5, 1985 (1060 O.G. 27).

- ☐ 37 C.F.R. 1.18 (issue fee at or before mailing of Notice of Allowance, pursuant to 37 C.F.R. 1.311 (b)).

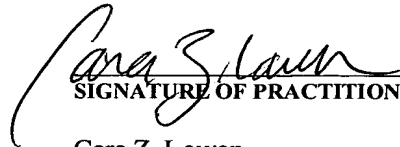
NOTE: Where an authorization to charge the issue fee to a deposit account has been filed before the mailing of a Notice of Allowance, the issue fee will be automatically charged to the deposit account at the time of mailing the notice of allowance. 37 CFR 1.311(b).

NOTE: 37 CFR 1.28(b) requires "Notification of any change in loss of entitlement to small entity status must be filed in the application . . . prior to paying, or at the time of paying . . . issue fee." From the wording of 37 CFR 1.28(b): (a) notification of change of status must be made even if the fee is paid as "other than a small entity" and (b) no notification is required if the change is to another small entity

☒ 37 C.F.R. 1.492(e) and (f) (surcharge fees for filing the declaration and/or an English translation of an international application later than 20 months from the earliest claimed priority date)

WARNING: It is suggested that you always check this last authorization.

Reg. No. 38,227


SIGNATURE OF PRACTITIONER

Cara Z. Lowen

(type or print name of practitioner)

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Boston, MA 02209
P.O. Address

178420



JC14 Rec'd PCT/PTO 28 SEP 2001

Docket No: 46342/55,965

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of: T. Ito, et al.
Serial No: 09/857,815
Filed: June 8, 2001
For: BETACELLULIN MUTEIN

CERTIFICATE OF MAILING

I hereby certify that this paper (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231 on September 25, 2001.

By: 

Donna M. Tomaso

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

TRANSMITTAL LETTER

Applicants submit the following documents as follows:

1. Submission Of "Sequence Listing", Computer Readable Copy, And/Or Amendment Pertaining Thereto For Biotechnology Invention Containing Nucleotide And/Or Amino Acid Sequence (Transmittal);
2. Copy of Notification of Missing Requirements and copy of Notice To Comply with Requirements dated July 25, 2001;
3. 3.5" Floppy Disk Containing the Sequence Listing,

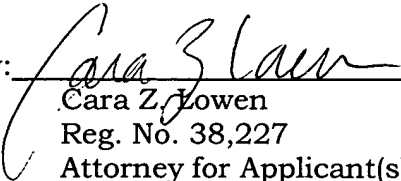
T. Ito, et al.
USSN: 09/857,815
Page 2

4. Statement In Support Of Filing And Submission In Accordance With 37 CFR §§1.821-1.825 And Sequence Listing Computer Printout;
5. Preliminary Amendment and Substitute Pages (Sheets 1-15).

Respectfully submitted,

Date: September 25, 2001

By: _____


Cara Z. Lowen
Reg. No. 38,227
Attorney for Applicant(s)

Dike, Bronstein, Roberts & Cushman
Intellectual Property Practice Group
EDWARDS & ANGELL, LLP
P.O. Box 9169
Boston, MA 02209
(617) 517-5536
178415



UNITED STATES PATENT AND TRADEMARK OFFICE

RECEIVED

JUL 27 2001

Commissioner for Patents, Box PCT
United States Patent and Trademark Office
Washington, D.C. 20231
www.uspto.gov

U.S. APPLICATION NO.

09/857815

FIRST NAMED APPLICANT

ITO

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ATTY. DOCKET NO.

46342/55965

INTERNATIONAL APPLICATION NO.

PCT/JP99/06873

I.A. FILING DATE

08 DEC 99

PRIORITY DATE

09 DEC 98

DAVID G. CONLIN
DIKE BRONSTEIN ROBERTS & CUSHMAN
EDWARDS & ANGELL
P.O. BOX 9169
BOSTON, MA 02209

DATE MAILED: 25 JUL 2001

NOTIFICATION OF MISSING REQUIREMENTS UNDER 35 U.S.C. 371 IN THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US)1. The following items have been submitted by the applicant or the IB to the United States Patent and Trademark Office as ☐ a Designated Office (37 CFR 1.494) ☒ an Elected Office (37 CFR 1.495):

- ☒ U.S. Basic National Fee. ☐ Indication of Small Entity Status.
☒ Copy of the international application. ☒ Translation of the international application into English.
☒ Oath or Declaration of inventors(s). ☐ Translation of Article 19 amendments into English.
☐ Copy of Article 19 amendments. ☐ Other:
☒ Priority Document.
☒ The International Preliminary Examination Report in English and its Annexes, if any.
☐ Translation of Annexes to the International Preliminary Examination Report into English.

2. ☐ Applicant has requested early processing under 35 U.S.C. 371(f) but has not filed the following indicated items and/or the indicated items in paragraph 3 below. The Basic National Fee and the copy of the international application must be filed prior to 20 or 30 months from the priority date to avoid abandonment.

- ☐ U.S. Basic National Fee. ☐ Copy of the international application.

3. The following items **MUST** be furnished within the period set forth below in order to complete the requirements for acceptance under 35 U.S.C. 371:

- ☐ a. Translation of the application into English. A processing fee will be required if submitted later than the appropriate 20 or 30 months from the priority date.
☐ The current translation is defective for the reasons indicated on the attached Notice of Defective Translation.
☐ b. Processing fee for providing the translation of the application and/or the Annexes later than the appropriate 20 or 30 months from the priority date (37 CFR 1.492(f)).
☐ c. Oath or declaration of the inventors, in compliance with 37 CFR 1.497(a) and (b), properly identifying the application (preferably by the International application number and international filing date). A surcharge will be required if submitted later than the appropriate 20 or 30 months from the priority date.
☐ The current oath or declaration does not comply with 37 CFR 1.497(a) and (b) for the reasons indicated on the attached PCT/DO/EO/917.
☐ d. Surcharge for providing the oath or declaration later than the appropriate 20 or 30 months from the priority date (37 CFR 1.492(e)).

4. Additional claim fees of \$ _____ as a ☐ large entity ☐ small entity, including any required multiple dependent claim fee, are required. Applicant must submit the additional claim fees or cancel the additional claims for which fees are due (37 CFR 1.492(g)). See attached PTO-875.5. ☒ Applicant has not submitted the required sequence listing pursuant to 37 CFR 1.821-1.825. See attached PCT/DO/EO/920.**ALL OF THE ITEMS SET FORTH IN 3(a)-3(d), 4 AND 5 ABOVE MUST BE SUBMITTED WITHIN TWO (2) MONTHS FROM THE DATE OF THIS NOTICE OR BY 22 OR 32 MONTHS (where 37 CFR 1.495 applies) FROM THE PRIORITY DATE FOR THE APPLICATION, WHICHEVER IS LATER. FAILURE TO PROPERLY RESPOND WILL RESULT IN ABANDONMENT.**

The time period set above may be extended by filing a petition and fee for extension of time under the provisions of 37 CFR 1.136(a).

6. If box 3a or 3c is checked, a translation of the Annexes **MUST** be submitted no later than the time period set above or the Annexes will be cancelled. A processing fee will be required if submitted later than 20 or 30 months from the priority date.
7. ☐ The Article 19 amendments are cancelled since a translation was not provided by the appropriate 20 (37 CFR 1.494(d)) or 30 (37 CFR 1.495(d)) months from the priority date.

Applicant is reminded that any communication to the United States Patent and Trademark Office must be mailed to the address given in the heading and include the U.S. application no. shown above. (37 CFR 1.5)

A copy of this notice MUST be returned with this response.Enclosed: ☐ PCT/DO/EO/917☐ Notice of Defective Translation☐ PTO-875☒ PCT/DO/EO/920

Barbara A. Campbell

FORM PCT/DO/EO/905 (March 2001)

Telephone: 703-305-3631

Sequence listing
Edwards & Angell LLP
Dike, Bronstein, Roberts & Cushman
130 Water St. Boston, MA 02108

Date Rec'd. 7/25/01

Docketed For 7/25/01

By KKD

Approved [Signature]

CCL/3/01



UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents, Box PCT
United States Patent and Trademark Office
Washington, D.C. 20231
www.uspto.gov

U.S. APPLICATION NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/857815	ITO	T 46342/55965
INTERNATIONAL APPLICATION NO.		
PCT/JP99/06873		
I.A. FILING DATE	PRIORITY DATE	
08 DEC 99	09 DEC 98	

DAVID G. CONLIN
DIKE BRONSTEIN ROBERTS & CUSHMAN
EDWARDS & ANGELL
P.O. BOX 9169
BOSTON, MA 02209

DATE MAILED: 25 JUL 2001

**NOTIFICATION TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS
CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE
DISCLOSURES**

Applicant has submitted papers under 35 U.S.C. 371 to enter the national stage in the United States of America. The items indicated below, however, are missing. The period within which to correct the deficiency noted below and avoid abandonment is set forth in the accompanying Notification.

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 CFR 1.821-1.825 for the following reason(s):

- ☒ The application fails to comply with the requirements of 37 CFR 1.821-1.825.
- ☐ This application does not contain, a "Sequence Listing" as a separate part of the disclosure on paper copy or compact disc, as required by 37 CFR 1.821(c).
- ☒ A copy of the "Sequence Listing" in computer readable format has not been submitted as required by 37 CFR 1.821(e).
- ☐ A copy of the "Sequence Listing" in computer readable form has been submitted. The content of the computer readable form, however, does not comply with the requirements of 37 CFR 1.822 and/or 1.832, as indicated on the attached marked-up copy of the "Raw Sequence Listing."
- ☐ The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A substitute computer readable form must be submitted as required by 37 CFR 1.825(d).
- ☐ The paper copy or compact disc of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 CFR 1.821(e).
- ☐ Other: _____

APPLICANT MUST PROVIDE:

- ☒ An initial or substitute computer readable form (CRF) of the "Sequence Listing."
- ☐ An initial or substitute paper copy or compact disc of the "Sequence Listing," as well as an amendment directing its entry into the specification.
- ☒ A statement that the contents of the paper or compact disc and the computer readable form are the same and, where applicable, include no new matter, as required by 37 CFR 1.821(e), 1.821(f), 1.821(g), 1.825(b) or 1.825(d).

FOR QUESTIONS REGARDING COMPLIANCE WITH THESE REQUIREMENTS, PLEASE
CALL:

(703) 308-4216, for Rules interpretation,
(703) 308-4212, for CRF submission help,
(703) 287-0200, for PatentIn software help.

Barbara A. Campbell
Telephone: 703-305-3631

BEST AVAILABLE COPY